A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy and Safety of Obinutuzumab in Patients with ISN/RPs 2003 Class III or IV Lupus Nephritis (REGENCY)

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 18 Years to 75 Years old
This study is NOT accepting healthy volunteers
Key

Inclusion Criteria:

• Diagnosis of active or active/chronic ISN/RPS 2003 Class III or IV proliferative LN as evidenced by renal biopsy performed within 6 months. Participants may co-exhibit Class V disease in addition to either Class III or Class IV disease

• Urine protein to creatinine ratio greater than or equal to (>/=) 1 on a 24-hour collection

• Other inclusion criteria may apply Key

Exclusion Criteria:

• Pregnancy or breastfeeding

• Severe renal impairment or the need for dialysis or renal transplantation

• Receipt of an excluded therapy, including any anti-CD20 therapy less than 9 months prior to screening or during screening; or cyclophosphamide, tacrolimus, ciclosporin, or voclosporin during the 2 months prior to screening or during screening

• Significant or uncontrolled medical disease which, in the investigator's opinion, would preclude patient participation

• Known active infection of any kind or recent major episode of infection

• Intolerance or contraindication to study therapies

• Other exclusion criteria may apply

Conditions & Interventions

Interventions:
Drug: Obinutuzumab, Drug: MMF, Drug: Prednisone, Drug: Placebo, Drug: Methylprednisolone, Drug: Acetaminophen, Drug: Diphenhydramine
Conditions:
Lupus Nephritis

More Information

Description: Study to Evaluate the Efficacy and Safety of Obinutuzumab in Patients with ISN/RPS 2003 Class III or IV Lupus Nephritis
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Phase: Phase 3
IRB Number: STUDY00010015
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